

Claims:

1. A biodegradable copolymer suitable for delivering a nucleic acid molecule to a cell, the copolymer comprising low molecular weight polyethylenimine cross-linked by a cyclodextrin.
2. The biodegradable copolymer according to claim 1 having a net positive charge and being capable of complexing with negatively charged nucleic acid molecules.
3. The biodegradable copolymer according to claim 2 wherein the net positive charge is provided by one or more of primary, secondary and tertiary amines.
4. The biodegradable copolymer according to any one of claims 1 to 3 wherein the low molecular weight polyethylenimine has a molecular weight of less than about 25000.
5. The biodegradable copolymer according to claim 4 wherein the polyethylenimine has a molecular weight of less than about 20000, preferably less than about 15000, more preferably less than about 10000, even more preferably less than about 5000.
6. The biodegradable copolymer according to claim 4 wherein the polyethylenimine has a molecular weight of less than about 2000.
7. The biodegradable copolymer according to claim 6 wherein the polyethylenimine has a molecular weight from about 600 to 2000.
8. The biodegradable copolymer according to any one of claims 1 to 7 wherein the cyclodextrin is  $\beta$ -cyclodextrin modified or activated by an agent to allow attachment to polyethylenimine.
9. The biodegradable copolymer according to claim 8 wherein the agent is selected from the group consisting of  $\beta$ -1,1'-carbonyldiimidazole, benzotriazole carbonate, N,N'-disuccinimidyl carbonate, chloroformates, N-hydroxysuccinimidyl chloroformate, and carbonylimidazole.
10. The biodegradable copolymer according to claim 9 wherein the agent is  $\beta$ -1,1'-carbonyldiimidazole.
11. The biodegradable copolymer according to any one of claims 1 to 10 wherein the polyethylenimine is cross-linked to cyclodextrin via a carbonyl group.
12. The biodegradable copolymer according to claim 11 having ester bonding.
13. The biodegradable copolymer according to any one of claims 1 to 12 wherein the copolymer contains up to about 35 polyethylenimine units.

14. The biodegradable copolymer according to claim 13 wherein the copolymer contains between about 5 and 25 polyethylenimine units.
15. The biodegradable copolymer according to claim 14 wherein the copolymer contains about 10 to 15 polyethylenimine units.
- 5 16. A method for synthesizing a biodegradable copolymer comprising the steps of:
  - (a) treating cyclodextrin with an agent to form a modified or activated cyclodextrin; and
  - (b) adding the modified or activated cyclodextrin to a low molecular weight polyethylenimine to form a mixture and treating the mixture under  
10 suitable conditions to form a biodegradable copolymer comprising polyethylenimine linked by cyclodextrin.
17. The method according to claim 16 wherein the cyclodextrin is  $\beta$ -cyclodextrin.
18. The method according to claim 17 wherein the agent is selected from the group consisting of  $\beta$ -1,1'-carbonyldiimidazole, benzotriazole carbonate, N,N'-  
15 disuccinimidyl carbonate, chloroformates, N-hydroxysuccinimidyl chloroformate, and carbonylimidazole.
19. The method according to claim 16 wherein the agent is  $\beta$ -1,1'-carbonyldiimidazole.
20. The method according to any one of claims 16 to 19 wherein the low molecular  
20 weight polyethylenimine has a molecular weight of less than about 25000.
21. The method according to claim 20 wherein the polyethylenimine has a molecular weight of less than about 20000, preferably less than about 15000, more preferably less than about 10000, even more preferably less than about 5000.
22. The method according to claim 20 wherein the polyethylenimine has a molecular  
25 weight of less than about 2000.
23. The method according to claim 22 wherein the polyethylenimine has a molecular weight from about 600 to 2000.
24. The method according to any one of claims 16 to 23 wherein the polyethylenimine is cross-linked to cyclodextrin by a carbonyl group.
- 30 25. The method according to claim 24 wherein the copolymer contains ester bonding.
26. The method according to any one of claims 16 to 25 wherein the copolymer contains up to about 35 polyethylenimine units.
27. The method according to claim 26 wherein the copolymer contains between  
35 about 5 and 25 polyethylenimine units.

28. The method according to claim 27 wherein the copolymer contains about 10 to 15 polyethylenimine units.
29. A biodegradable copolymer synthesized by the method according to any one of claims 16 to 28.
- 5 30. A method for delivering a nucleic acid molecule to a cell, the method comprising forming a complex between a biodegradable copolymer according to any one of claims 1 to 15 and a nucleic acid molecule and exposing the cell to the copolymer / nucleic acid molecule complex such that the complex is internalized by the cell and the nucleic acid molecule is released in the cell.
- 10 31. The method according to claim 30 wherein the cell is in an animal.
32. The method according to claim 31 wherein the animal is a human.
33. A method for delivering a nucleic acid molecule to a cell, the method comprising forming a complex between a biodegradable copolymer according to claim 29 and a nucleic acid molecule and exposing the cell to the copolymer / nucleic acid molecule complex such that the complex is internalized by the cell and the nucleic acid molecule is released in the cell.
- 15 34. The method according to claim 33 wherein the cell is in an animal.
35. The method according to claim 34 wherein the animal is a human.
36. Use of a biodegradable copolymer according to any one of claims 1 to 15 to deliver a nucleic acid molecule to a cell.
- 20 37. Use of a biodegradable copolymer according to claim 29 to deliver a nucleic acid molecule to a cell.
38. Use of a biodegradable copolymer according to any one of claims 1 to 15 in the manufacture of a medicament for the delivery of a nucleic acid molecule to a cell in an animal.
- 25 39. Use of a biodegradable copolymer according to claim 29 in the manufacture of a medicament for the delivery of a nucleic acid molecule to a cell in an animal.